REMARKS

Claims 1, 3-14, 32 and 38-55 were examined. Claims 1, 7 and 38 are amended. Claims 1, 3-14, 32 and 38-55 remain in the Application.

I. Claim Amendments

Claims 1 and 38 are amended to describe a delivery lumen (claim 1) and a delivery device (claim 38) coupled to an exterior surface of a balloon and inflating a balloon to pivot a portion of the delivery lumen from a first position toward a direction of a wall of a blood vessel (claim 1) or pivoting from a first position toward a wall of a blood vessel (claim 38). Support for the amendments may be found in the Application at, for example, paragraph [0082].

II. Claim Rejections – 35 U.S.C. §112

Claims 7 is rejected under 35 U.S.C. §112 as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 7 is amended to address the concern raised by the Patent Office. Applicant respectfully requests that the Patent Office withdraw the rejection of claim 7 under 35 U.S.C. §112, second paragraph.

III. Claim Rejections – 35 U.S.C. §103

A. Claims 1, 3, 5-14, 38-43, 46-48 and 51-53 are rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,602,241 issued to Makower, et al. ("Makower") in view of U.S. Patent No. 6,726,677 of Flaherty, et al. (Flaherty) or U.S. Patent No. 5,672,153 of Lax, et al. (Lax).

It is axiomatic to a finding of anticipation that each and every element of the rejected claim be found within a single prior art reference.

Independent claim 1 recites:

> A method comprising:
> positioning a distal portion of a delivery device at a location in a blood vessel the distal portion of the delivery device comprising a balloon and a delivery lumen coupled to an exterior surface of the balloon;

imaging a thickness of at least a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a second lumen of the delivery device;

identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging;

inflating the balloon to cause a portion of the delivery lumen to pivot from a first position toward a direction of the wall of the blood vessel;

advancing a needle beyond the delivery lumen of the delivery device a distance into the wall of the blood vessel to the treatment site beyond the external elastic lamina of the blood vessel; and

after advancing the needle, introducing a treatment agent in a sustained release composition through the needle.

Applicant respectfully submits that the cited references fail to teach at least the elements of "a delivery lumen coupled to the balloon"; and "inflating the balloon to cause a portion of the delivery lumen to pivot from a first position toward a direction of the wall of the blood vessel"; and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel ... and ... introducing a treatment agent thought the needle" as recited in amended claim 1.

Makower does not describe a balloon associated with its device or a delivery lumen coupled to a balloon. Makower discloses catheter body 13 that has penetrator lumen 27 that terminates at exit location or port 29 on peripheral wall 31 of the body. A needle is disposed within lumen 27. See col. 7, lumen 48-56. Makower discloses advancing a needle through penetrator lumen 27 that exits a port in a peripheral wall of its catheter. Assuming penetrator lumen 27 is a delivery lumen, there is no teaching of it being caused to be moved. Presumably, penetrator lumen 27 is not caused to be moved but is stationary so as to be aligned with exit location or port 29 on the catheter. Further, Makower discloses penetrating catheter 11 having penetrator 85 that penetrates tissue. Delivery catheter 12 is then advanced through a lumen of penetrator 85. In contrast, claim 1 describes advancing a needle beyond a delivery lumen into a wall of a blood vessel and introducing a treatment agent through the needle. The needle is penetrating as opposed to penetrator 85 in Makower.

Flaherty discloses various tissue penetrating catheter and embodiments disclosed with reference to at least Figures 3-5C show balloons associated with the catheter. In each of the embodiments, the path of the working lumen of the catheter is defined independent of the balloon in Figures 4A-4B, for example, the path in catheter body 102 is defined to a have a side opening. Inflation of balloon 114 puts the side opening adjacent a wall of blood vessel 120. The balloon does not pivot lumen 106.

Similar to Flaherty, Lax describes a catheter including a balloon and stylets. In reference to Figure 6, the stylets travel in guide paths 136. Guide paths 136 are not altered by the balloon.

Since the cited references fail to teach each and every element or provide any suggestion, motivation, or prediction for the elements of independent claim 1, claim 1 is not anticipated by the cited prior art reference. Applicants respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a).

Independent claim 38 provides:

> A method comprising:
> positioning a distal portion of a delivery device at a location in a blood vessel the distal portion of the delivery device coupled to an exterior surface of a balloon;
> imaging a thickness of at least a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a lumen of the delivery device;
> pivoting the distal portion of the delivery device from a first position toward the portion of the wall of the blood vessel by inflating the balloon;
> advancing a needle beyond the distal portion of the delivery device a distance into the wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and
> after advancing the needle, introducing a treatment agent through the needle,
>
> wherein the treatment agent comprises an inflammation-inducing agent.

Claim 38 is not obvious over the cited references because the combination fails to teach or provide any motivation or prediction for at least pivoting a distal portion of a delivery device from a first position toward a portion of a wall of a blood vessel by inflating a balloon. The analysis presented above with regard to the references and claim 1 is relevant and incorporated

here. In particular, inflating the balloon in Flaherty and Lax do not result in pivoting of a delivery device. Claim 38 is not obvious over the cited references.

Claims 3, 5-14 and 46-48 depend from claim 1 and 39-43 and 51-53 depend from claim 38 and therefore contain all the limitations of that respective claim. For at least the reasons stated in respect to claim 1 or 38, claims 3, 5-14, 39-43, 46-48 and 51-53 are not obvious.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 38-43 and 51-53 under 35 U.S.C. §103(a).

Claims 4, 32 and 54 are rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent Makower in view of Flaherty or Lax.

Claims 4 and 32 depend from claim 1 and claim 54 depends from claim 38. As noted above, Makower, Flaherty and Lax do not disclose the limitations of "a delivery lumen coupled to the balloon"; "inflating the balloon to cause a portion of the delivery lumen to pivot from a first position toward a direction of the wall of the blood vessel"; and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel ... and ... introducing a treatment agent through the needle," or "pivoting the distal portion of the delivery device from a first position toward the portion of the wall of the blood vessel by inflating the balloon" as in claim 38. Selmon further fails to cure the deficiencies of the other references with respect to these elements. Thus, for at least the foregoing reasons, claims 4, 32 and 54 are not obvious over the cited prior art references. Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 4, 32 and 52 under 35 U.S.C. §103(a).

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of Flaherty or Lax and further in view of U.S. Patent Publication No. 2002/0131974 of Segal ("Segal").

In regard to claim 11, this claim depends from claim 1 and incorporates the limitations thereof. For at least the reasons previously discussed, the cited references do not disclose the limitations of "a delivery lumen coupled to the balloon"; "inflating the balloon to cause a portion of the delivery lumen to pivot from a first position toward a direction of the wall of the blood vessel"; and "advancing a needle beyond the lumen of the delivery device a distance into the wall

of the blood vessel ... and ... introducing a treatment agent through the needle" as incorporated into claim 11 from claim 1. Segal does not cure these deficiencies of the other references with respect to these elements. Thus, for at least the foregoing reasons, claim 11 is not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. §103(a).

Claims 12-13, 41-43, 47 and 52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of Flaherty or Lax and further in view of U.S. Patent No. 5,749,915 issued to Slepian ("Slepian").

In regard to claims 12-13 and 47, these claims depend from claim 1 and incorporate the limitations thereof. Claims 41-43 and 52 depend from 38 and incorporate the limitations thereof. Slepian does not cure the deficiencies of Makower, Flaherty and Lax with respect to the elements of the independent claims. Thus, for at least the foregoing reasons, claims 12-13 and 47 are not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 12-13, 41-43, 47 and 52under 35 U.S.C. §103(a).

Claims 44-45 and 49-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of Flaherty or Lax and further in view of U.S. Patent No. 5,676,151 issued to Yock ("Yock") or U.S. Patent No. 6,338,717 issued to Ouchi ("Ouchi").

Claims 44-45 depend from claim 1 and incorporate the limitations thereof. Neither Yock nor Ouchi cure the deficiencies of the other references with respect to the elements of claim 1. Thus, for at least the foregoing reasons, claims 44-45 are further not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 44-45 under 35 U.S.C. §103(a).

Claim 55 is rejected under 35 U.S.C. §103(a) as obvious over Makower in view of Flaherty or Lax and further in view of U.S. Patent No. 5,725,551 of Myers et al. (Myers).

Myers describes an apparatus and method for sealing an arteriotomy site. Myers describes that wall thickness of a vessel can be determined using methods such as ultrasound or other imaging techniques.

Claim 55 depends from claim 1 and incorporates the limitations therefore. Thus, for at least the reasons that claim 1 is not obvious in view of the cited prior art references, claim 55 is not obvious. Claim 55 is further patentable for at least the reasons that the prior art of record fails to disclose the additional elements of "measuring the thickness of the portion of the wall of the blood vessel using the imaging assembly; and identifying the treatment site based on the imaging and measuring" as recited in claim 55. Myers is determining a thickness of a vessel so that it can seal an opening. As noted above, a thickness of a vessel wall is of no relevance to Makower. Therefore, there is no prediction of success to incorporate a determination of a vessel wall thickness in Myers to the technique of Makower.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon 1/23/2012

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